Declaration of Steffen Lav. The applicants respectfully request reconsideration of the rejection of claims 11-31 based on such Declaration and the following Remarks.

Claim Rejections: 35 U.S.C. § 112

Claims 11-30 stand rejected as failing to comply with Section 112. Specifically, the Examiner contends that there is no support for the limitation that the lancer is mounted "in" the housing in claim 1, and no support for the limitation that the second compartment is adapted to "receive and store" a lancer in claim 24.

The applicants contend that claims 1-30 are supported because the locking means 31 of the lancer extend into the interior of the cap unit 10. In rejecting that argument, the Examiner contends that "one cannot tell if the locking means 31 include a structure that extends from the lancer or is a recessed space (opening) that another member would [be] inserted into." May 5, 2005 Office Action pp. 2-3. The Examiner alternatively contends that the quadrilateral shape of the locking means 31 shown in the drawings could merely "depict a 'black box' element that depicts an entirely different intended structure." May 5, 2005 Office Action p. 3.

As explained in detail in the Lav declaration, because the specification discloses that the cap and lancer units "lock" together, a person skilled in the art would know that either the lancer unit or the cap unit must have an outwardly extending hook or similar member, and that such hook must extend into the interior

of the other component. A person skilled in the art would further understand that the latter option, i.e., placing the hook on the convex surface of the cap unit 10, would not be acceptable. Therefore, the hook or similar member must be on the concave surface of the lancer unit, i.e., locking means 31 must be a hook or the like.

Addressing the Examiner's alternate contention, even if a person skilled in the art were to consider element 31 to be a "black box," i.e., not a depiction of the exact structure intended, a person skilled in the art would still understand that, at a minimum, whatever structure is used as the locking element 31 must include some type of hook or other projecting member that extends into the interior of the cap unit 10 – because without such hook or similar member, one could not "lock" the cap and lancer units together.

The applicants respectfully refer the Examiner to the Lav Declaration for a detailed explanation of why a person skilled in the art would conclude that locking means 31 must be a hook or similar structure. Reconsideration and withdrawal of the Section 112 rejection is respectfully requested.

Rejection Of Claim 31

Claim 31 stands rejected under 35 U.S.C. § 103(a) as obvious over Castellano et al. U.S. patent No. 5,728,074. Although Castellano does not disclose a

device in which the syringe is removable, the Examiner asserts that making the syringe removable would be obvious. The Examiner cites Application of Dulberg, 289 F.2d 522 (CCPA 1961) for the proposition that, because the Castellano syringe could be made detachable, it is obvious to do so.

The Office initially made a similar assertion in the parent case, except that the cited reference was Colman et al. U.S. patent No. 5,665,065, and the authority cited for the proposition that it is obvious to break up an integral device into separate components was Nerwin v. Erlichman, 168 U.S.P.Q. 177, 179 (Patent Office Bd. App. 1969). See Office Action dated January 27, 2000 in Ser. No. 09/312,796. However, as the applicants pointed out in the parent case, Erlichman cannot be read in a way which is inconsistent with Section 103 of the Patent Statute, which specifies that an applicant is entitled to a patent unless the claimed invention would have been obvious.

In the parent case, the Examiner withdrew the rejection, because Colman did not suggest a means for detachably assembling the elements. So too here, Castellano contains no suggestion of detachably coupling the syringe from the housing containing the monitor, or any suggestion of why that modification would have been desirable.

Like Erlichman, Dulberg does not support the proposition that it is obvious to modify a prior art device absent some suggestion in the art of a motivation

to do so. In Dulberg, the issue was whether it would have been obvious to modify the prior art, which disclosed a cap permanently affixed to a housing, to make the cap removable. The Dulberg Court stated,

> Whether a cap is made manually removable depends upon whether it is desired to gain ready access the space covered by the cap. If it were considered desirable for any reason to obtain access to the end of Peterson's holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.

Dulberg, 289 F.2d at 523. Thus, Dulberg did not hold that it would have been obvious to make the cap removable merely because that could be done. Rather, the Court required a motivation that a person skilled in the art would want access to that space.

Here, Castellano discloses no reason why a person skilled in the art would wish to make the syringe removable from the rest of the housing. To the contrary, Castellano seeks to change the prior art practice of providing a separate syringe, injector, and blood glucose monitor, Col. 1, ll. 30-35, to make an "all-in-one device." Abstract. Because Castellano teaches away from making the syringe a separate, detachable element, it cannot properly form the basis of a finding that it would have been obvious to make such modification.

In the May 5, 2005, Office Action, the Examiner asserts that it would be desirable to remove the pen of Castellano "upon failure of the pen to function while the rest of the system was still usable . . . " Office Action at p. 4. The applicants respectfully disagree.

First and foremost, if the pen fails, the rest of the system is not usable. The whole purpose of the Castellano device is to deliver insulin. Even if the bgm remains functional, and thus the user can accurately determine the size of insulin dosage needed, a bgm monitor cannot deliver insulin.

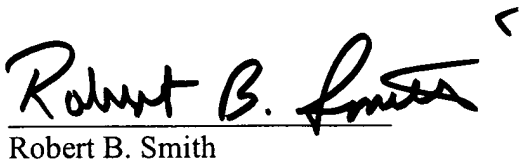
Secondly, were the pen to be removed, the Castellano device cannot function for its intended purpose – to obviate the need to carry around separate pen and bgm devices.

Finally, there is no disclosure in Castellano that the pen might fail, or that if so it can be removed without damaging the device. Thus, if the pen were to fail, a user would likely buy a replacement device. Even if the user decided to continue to use the bgm alone, there is no motivation for the user to try to remove the pen – the user would simply carry around the whole device. Thus, if the headphones jack on a stereo system were to fail, and the owner decided to continue to use the stereo only with speakers, he or she would be unlikely to rip out the jack. The user would simply leave it, just as a user of the Castellano device would leave the pen if the pen were to fail.

For the foregoing reasons, the applicants respectfully request that the rejection of claim 31 be withdrawn.

For the foregoing reasons, withdrawal of the rejections of claims 1-31 is respectfully requested.

Respectfully submitted,



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